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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,524	12/29/2003	Richard E. Parizek	I 1995.184 US D1	8568

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PATENT DEPARTMENT
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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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.1645

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/748,524	Applicant(s) PARIZEK ET AL.	
	Examiner Ja-Na Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,15,17-19,40 and 46-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,15,17-19,40 and 46-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. The amendment filed July 21, 2006 has been entered. Claims 1-3, 17, 19, 40, and 46-47 have been amended. Claims 4-14, 16, 20-39 and 41-45 have been cancelled. Claim 48 has been newly added. Claims 1-3,15, 17-19, 40 and 46-48 are under consideration in this office action.

Withdrawal of Rejections

2. The written description rejection of claims 1-3,15, 17-19, 40 and 46-47 under 35 U.S.C. 112, first paragraph has been withdrawn in view of applicants' amendments and arguments.

Response to Arguments

3. Applicant's arguments filed July 21, 2006 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. The rejection of claims 1-3,15, 17-19 and 40 under 35 U.S.C. 102(a) as being anticipated by Roberts (WO 94/22476) is maintained for reasons already of record. The

rejection was on the grounds that Roberts teach a multicomponent vaccine for ruminants comprising an immunologically effective combination of a protective antigen component from six or seven specifically recited clostridial organisms, a protective antigen from at least one non-clostridial gram-negative *M. bovis* and/or *H. somnus*, and a polymer adjuvant wherein the dose is 3 ml or less.

Applicants' assert Roberts' because the newly recited adjuvant is a polymer adjuvant which functions to release the antigen slowly, that Roberts does not anticipate the instant claims. However it is the examiner's position a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Furthermore, MPEP 2123 teaches that patents are relevant as prior art for all they contain, and that "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968).

Here, Roberts may be relied upon because it reasonably suggest to one having ordinary skill in the art the administration of multicomponent vaccines in low dose volumes of about 3 ml or less having dispersible, soluble adjuvants. Roberts states that potent adjuvants such as carbopol have been used in clostridial vaccines. Therefore, Roberts have disclosed the polymer adjuvant even though Roberts may refer to polymer

Art Unit: 1645

adjuvants as nonpreferred embodiments. Polymer adjuvants, including carbopol, are known to readily absorb water and due to its hydrophilic nature, and cross-linked structure, are known to useable for controlled release drug delivery systems. Carbopols were first prepared in 1957 and since then many extended release formulations have been presented in the art. Therefore, Roberts teaching of a dispersible, soluble adjuvant, encompasses polymer adjuvants, just as required by the claims.

Applicants' urge that because the claims now recite polymer adjuvants as the adjuvant, Roberts no longer anticipates the claims. However it is the examiner's position that because the instant claims recite the use of an adjuvant which is a polymer, Roberts still anticipate the claims. Roberts even cites prior art references teaching the adjuvants can be admixed in liposomes. The instant specification at page 15, lines 22-28, state that polymers, including liposomes are adjuvants that function by encapsulating the antigen and releasing them over a period of weeks to months. Roberts teaches: compositions using water dispersible, water soluble adjuvants; the previous use of carbopol with clostridial vaccines; and the use of polymer adjuvants such as liposomes. Finally, in response to applicant's argument that the polymer adjuvant functions by releasing antigen slowly, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Here, Roberts teaches a polymer adjuvant. Therefore applicants' assertions are

not persuasive and the rejection is maintained since Roberts discloses the use of polymer adjuvants.

5. The rejection of claims 46-48 under 35 U.S.C. 102(a) as being anticipated by Roberts (WO 94/22476) is maintained for reasons already of record. The rejection was on the grounds that Roberts teach a method of immunizing a bovine animal comprising administering an effective amount of the vaccine in claims 1 or 2, just as instantly claimed. However, for the reasons set forth above, the rejection of claims 46-48 is maintained.

Claim Objections

6. The objection of claims 46-48 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is maintained. Dependant claims 46-48 refer to a bovine animal, however claims 1 and 2 refer to cattle. Bovine is a broader term than cattle. Therefore, claims 46-47 do not further limit claims 1-2. Appropriate clarification is required to overcome the objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. The rejection of claims 46-48 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Art Unit: 1645

applicant regards as the invention is maintained for reasons already of record. The preamble of the claims is drawn to a method of immunizing a bovine animal, however the method recites administering the vaccine of claims 1 and 2 to cattle. The vaccines are for cattle and not bovine which are a broader class and encompass more than just cattle. Bovine includes a diverse group of about 24 species of medium-sized to large ungulates, including domestic cattle, bison, the water buffalo, the yak, and the four-horned and spiral-horned antelopes. Therefore the goal of the preamble is not commensurate with the steps of the method drawn to bovines and not just cattle.

Conclusion

8. No claims allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, A. Mark Navarro can be reached on 571-272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 
September 29, 2006


MARK NAVARRO
PRIMARY EXAMINER